1 September 2014

Draft background document for Lead Monoxide

Document developed in the context of ECHA's 6th Recommendation for the inclusion of substances in Annex XIV

ECHA is required to regularly prioritise the substances from the Candidate List and to submit to the European Commission recommendations of substances that should be subject to authorisation. This document provides background information on the prioritisation of the substance, as well as on the determination of its draft entry in the Authorisation List (Annex XIV of the REACH Regulation). Information comprising confidential comments submitted during public consultation, or relating to content of Registration dossiers which is of such nature that it may potentially harm the commercial interest of companies if it was disclosed, is provided in a confidential annex to this document.

1. Identity of the substance

Chemical name: Lead monoxide
EC Number: 215-267-0
CAS Number: 1317-36-8
IUPAC Name: Lead monoxide

2. Background information for prioritisation

Priority was assessed by using the General approach for prioritisation of SVHCs for inclusion in the list of substances subject to authorisation[1]. Results of the prioritisation of all substances included in the Candidate List by June 2013 or before and not yet included or recommended in Annex XIV of the REACH Regulation is available at http://echa.europa.eu/documents/10162/13640/prioritisation_results_6th_rec_en.pdf .

2.1. Intrinsic properties

Lead monoxide was identified as a Substance of Very High Concern (SVHC) according to article 57 (c) as it is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Toxic for Reproduction, Category 1A, [H360D ("May damage the unborn child")], and was therefore included in the candidate list for authorisation on 19/12/2012, following ECHA's decision ED/169/2012.

2.2. Volume used in the scope of authorisation

The amount of lead monoxide manufactured and/or imported into the EU is according to registration data above 100,000 t/y.

[1] Document can be accessed at http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf

Some uses appear not to be in the scope of authorisation, such as use in manufacturing of PVC stabilisers, certain pigments, explosives and technical ceramics, and use as laboratory reagent and in chemical analysis. The volume used in glass and frits is taken into account when allocating the volume score. It is recognized that the intermediate/non-intermediate status of these uses is a complex issue, and stressed that this prioritisation exercise is not taking a formal position whether certain uses of substances are regarded as uses as intermediates in accordance with the definition in article 3(15). It is further noted that whether or not the use in glass and frits is taken into account does not ultimately change the volume score.

Taking into account the volume corresponding to uses appearing to fall outside the scope of authorisation from the registration dossiers and other information, the volume in the scope of authorisation is estimated to be in the range of 100,000 - 1,000,000 t/y.

2.3. Wide-dispersiveness of uses

Registered uses of lead monoxide which appear to be in the scope of authorisation include uses at industrial sites (e.g. batteries, rubber, adsorbents). In addition, according to the information from the industry (RCOM, 2012) the substance can be used in graphite containing dispersion pastes, machining, scraping compounds, friction breaks, and sealants. There is no further information on these uses and therefore it is not possible to conclude whether the uses take place at industrial sites or whether some of them could be carried out by professional workers.

The lead registrant and most of the member registrants have recently updated their registrations. They have, inter alia, removed the professional and consumer use of paints and pigments (e.g. artists' paints2) containing lead monoxide from their registrations and they have clarified that the use of adsorbents is industrial rather than professional. The International Lead Association has also informed ECHA of the relevant updates to the registration dossiers. However, there are some members who have not yet updated their registrations, and the professional and consumer uses in paints (and professional use of adsorbents) remain in their dossiers. These members refer to the lead registrant's CSR which no longer supports these uses.

Finally, according to registrations the substance is used in articles and information provided by industry (RCOM, 2012) indicates that this is in volumes above 10 t/y (e.g. rubber articles).

Further information on uses is provided in Section 3.

[2] This use is derogated from the restriction to supply CMR substances on their own or in mixtures to the general public.

2.4. Conclusions and justification

Verbal descriptions and Scores			Total Score
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)	(= IP + V + WDU)
Lead monoxide is classified as toxic for reproduction 1A meeting the criteria 57c Score: 1	The amount of lead monoxide used in the scope of authorisation is in the range of 100,000 – 1,000,000 t/y Score: 15	Lead monoxide is used at industrial sites Initial score: 5 Furthermore, the substance is potentially used by professional workers and might also be used by consumers in uses that may also be in the scope of authorisation[3]. Finally the substance is used in articles in volumes > 10 t/y (e.g. rubber articles) Refined score: 7- 10	23-26

Conclusion

On the basis of the prioritisation criteria, lead monoxide received high priority among the substances in the Candidate List (refer to link to the prioritisation results above). Therefore, it is proposed to recommend lead monoxide for inclusion in Annex XIV.

3. Further information on uses

In addition to the registration information, further details on uses can be found in comments provided during the SVHC public consultation (RCOM, 2012).

Lead monoxide has several different uses in a range of EU industries. However, the production of lead-acid batteries represents the main use of lead monoxide since it represents over 90% of its total use based on information from industry (RCOM, 2012). The (intermediate) use of lead monoxide in manufacture of lead based PVC stabilisers comprises most of the rest of the relative share (though the use of these stabilisers is being phased out due to an industry voluntary commitment - VinylPlus). All the other uses represent less than 1% of the total volume (RCOM, 2012). However, as the total EU tonnage is high, the tonnage corresponding to some of the uses representing low relative share may still be in the range of tens, hundreds or even thousands of tons per year.

The estimated volumes corresponding to different uses of lead monoxide in the scope of authorisation based on the information from the registrations and from industry during the SVHC public consultation (RCOM, 2012) are given below:

- in lead acid battery production: it is used in the production of battery plates used in automotive and industrial batteries (>400,000 t/y);
- as a vulcanizing agent in the rubber industry (<200 t/y)
- in adsorbents (unknown tonnage)

Furthermore, uses which may be in the scope of authorisation include

- in production of domestic glass (which includes crystal glass), and Special Glass (e.g. radiation shielding glass) (less than 5,000 t/y);
- in manufacture of frits (approx. 1.000 t/y);

[3] See Section 2.3 for more information

In addition, during the SVHC public consultation, industry stated that < 500 t/y of lead monoxide can be used in graphite containing dispersion pastes, machining, scraping compounds and friction brakes (RCOM, 2012) and also an industrial use in sealants was identified.

Further information on some of the above listed uses is given below.

Use in the production of batteries
In lead acid battery production, lead monoxide is used in the production of battery pastes and it is transformed in the course of the battery production process into pentalead tetraoxide sulphate and tetralead trioxide sulphate, and then ultimately into lead metal (Pb) and lead dioxide (PbO2). The latter two substances are the lead-based active substances present in the battery. Chemical reactions for lead monoxide occur throughout the battery production process and at the final stage of the process when the battery is charged the substance has fully reacted and in most lead based batteries only some residual concentrations remain in the final article (further details on battery production available in ILA and EUROBAT comments - RCOM, 2012).

Lead-based batteries are widely used in automotive vehicles and industrial motive and standby applications, e.g. in forklift trucks and electric wheelchairs, as Uninterruptible Power Supply (UPS) for hospitals, IT applications and telecommunication systems including both landline and mobile telephone base station applications (RCOM, 2012). It is reported that approximately one third of the tonnage of lead monoxide used in batteries is used in industrial batteries and the remaining two thirds in automotive batteries (RCOM, 2012). Key countries for lead-based battery manufacture in Europe include France, Germany, Italy, Spain, Poland, the Czech Republic, Portugal and the UK.

Use in the production of glass
Lead monoxide is used in the production of domestic and special glass. The EU glass industry represents ca. 1,200 companies (including SMEs to multinationals). Special glass represents roughly 2% of the total EU glass production. In the production of special glass lead monoxide is used for a wide variety of glasses, e.g. lead protection glass, lead ophthalmic glass, optical glasses, lead flint glass, nuclear shielding protection windows/blocs. Lead monoxide is the source of lead, and is used to achieve protection against gamma radiation. Lead monoxide is required for producing glass that allows safe use of modern medicine (x-ray application) and safe use of nuclear power supply (RCOM, 2012). Key countries for glass manufacture in Europe include Austria, Belgium, France, Germany, Italy, Spain, Poland and the Czech Republic.

Use in the manufacture of frits
Lead monoxide is used in the manufacture of frits which are then used for preparation of ceramic glazes. Lead monoxide is not used directly for ceramic glazes. Lead-containing frits have specific characteristics. They heal the pin-holes in the glaze during the firing stage to ensure a smooth surface, they allow the glazes to be fired at lower temperatures and create a more uniform glaze and they also enhance the colours used for decoration. According to information from the industry (RCOM, 2012), frits are not manufactured at the same sites as the ceramic articles. It is estimated that there are around 60 installations in the EU manufacturing frits for glazes and enamels, mostly in Spain and Italy, though this figure could include those manufacturing frits from other substances than lead monoxide. The lead-containing frits are widely used in the ceramics sector for the production of roof tiles, wall and floor tiles, sanitary ware, and table and ornamental ware. There are more than 1,000 companies using frits.

Use in the manufacture of rubber
Lead monoxide is currently used in the rubber industry as:

- An ingredient of compounds for rubber rollers, valves and accessories where lead

monoxide is incorporated into the rubber compound and acts as an antioxidant, especially in contact with acids and/or steam;

- An ingredient of compounds for membranes where lead monoxide reduces water absorption in rubber compounds;
- An ingredient of rubber compounds for hoses where lead monoxide acts as a vulcanizing agent; and
- An ingredient of rubber compounds for steel cable conveyor belts, in which lead monoxide acts as an adhesion promoter and corrosion inhibitor.

The rubber products described above, in which lead monoxide is used, are used by a number of sectors including: the chemical industry; gas pipe installations; mining industry; automotive industry; cement industry; power plants; ports and inflatable structures manufacturers. Industry indicates that lead monoxide is used in the manufacture of rubber compounds at 17 European sites located in Germany, the Czech Republic, Slovakia and Greece (RCOM, 2012).

4. Background information for the proposed Annex XIV entry

Draft Annex XIV entries were determined on the basis of the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV[4]. The draft Annex XIV entries for substances included in this draft recommendation are available at http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_summarytable_6th_en.pdf *. The section below provides background for allocation of the substance to the Latest Application Date slots.*

The LAD slots are set in 3 months intervals (i.e. 18, 21 and 24 months after inclusion in Annex XIV).

Lead substances have been considered to be placed in the same slot as they may fulfil the definition of a group according to section 1.5 of Annex XI of REACH (provision allowing submitting common applications for authorisation).

The allocation of (group of) substances to LAD slots aims at an even workload for all parties during the opinion forming and decision making on the authorisation applications. The differences between the total time for preparing the application (i.e. 18, 21 and 24 months) can be regarded minor. However, substances for which the preparation of the application may require longer time are assigned to the later LAD slots (2nd and 3d).

Lead substances (including lead monoxide) are assigned to the 2nd LAD slot due to the potentially high number of uses and overall complexity of supply chain.

5. References

RCOM (2012):"*Responses to comments*" document. Document compiled by ECHA from the commenting period 03/09/2012-18/10/2012 on the proposal to identify lead monoxide as a Substance of Very High Concern. http://echa.europa.eu/candidate-list-table/-/substance/2427/search/215-267-0/term

[4] Document can be accessed at http://echa.europa.eu/documents/10162/13640/draft_axiv_entries_gen_approach_6th_en.pdf